Individual Safety Report

*3307338-X-00-01*

McNeil Consumer Healthcare

McNeil Consumer Healthcare
rt Washington, PA 19034-2299

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Approved by FDA on 11/15/93

Mfr report #

UF/Distr report #

FDA use only

## A. Patient information

| 1. Patient identifier | 2. Age at time of event: / or Date of birth: | 3. Sex | 4. Weight |
|---|---|---|---|
| Case 240 In confidence | 39 yrs | (X) female ( ) male | unk lbs or kgs |

## B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (x) death unknown (mo/day/yr)
- ( ) life-threatening
- (x) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

| 3. Date of event | 4. Date of this report |
|---|---|
| unknown (mo/day/yr) | 07/09/99 (mo/day/yr) |

5. Describe event or problem

Pre-publication copy of the 1998 annual report from the American Association of Poison Control Centers TESS database of human exposure cases reported by 65 participating centers during 1998. Information provided in report indicates Case 240 was a 39-year-old woman who presented with a history of NAUSEA AND VOMITING & admitted to taking 10 to 14 tablets of acetaminophen (500 mg/tab) daily for several days (ACCIDENTAL OVERDOSE). Reason for exposure listed as therapeutic error. Her PMH included alcoholic liver disease but current ethanol intake was unknown. Initial laboratory results showed: AST=13,500 U/L, PT=100 sec; & INR=11. Plasma acetaminophen concentration was 27 mcg/ml an unknown time after the last dose. Over the next 24 hours the patient received NAC via nasogastric tube but became encephalopathic (ENCEPHALOPATHY) & unresponsive (STUPOR). Her ammonia concentration reached 520 mcg/dl & she expired (DEATH). Addl info rec'd 7/7/99: Case 240 rec'd from the AAPCC 1998 case fatality data indicates patient was taking Extra Strength TYLENOL®.

6. Relevant tests/laboratory data, including dates

Initial laboratory results showed: AST=13,500 U/L; PT=100 sec; and INR=11. Plasma acetaminophen concentration was 27 mcg/ml an unknown time after the last dose. Ammonia concentration reached 520 mcg/dl.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

past medical history included alcoholic liver disease but current ethanol intake was unknown

DSS

JUL 20 1999

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product

#2 ethanol

| 2. Dose, frequency & route used | 3. Therapy dates (if unknown, give duration) from/to (or best estimate) |
|---|---|
| #1 5 to 7 grams, qd, po | #1 several days |
| #2 current intake unknown | #2 unknown |

| 4. Diagnosis for use (indication) | 5. Event abated after use stopped or dose reduced |
|---|---|
| #1 therapeutic error | #1 ( ) Yes ( ) No (X) N/A |
| #2 therapeutic error | #2 ( ) Yes ( ) No (X) N/A |

| 6. Lot # (if known) | 7. Exp. date (if known) | 8. Event reappeared after reintroduction |
|---|---|---|
| #1 unknown | #1 unknown | #1 ( ) Yes ( ) No (X) N/A |
| #2 Unknown | #2 Unknown | #2 ( ) Yes ( ) No (X) N/A |

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

## G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- (x) literature
- ( ) consumer
- (x) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 07/07/99

5.
- (A) NDA # 19-872
- IND #
- PLA #
- pre-1938 ( ) Yes
- OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- ( ) Initial (X) follow-up # 1

8. Adverse event term(s)

DEATH
ENCEPHALOPATHY
OVERDOSE ACCID
NAUSEA VOMIT
STUPOR

9. Mfr. report number: 1191210A

## E. Initial reporter

1. Name, address & phone #

Toby L. Litovitz, MD
Amer Assoc Poison Control Centers
3201 New Mexico Avenue, Suite 310
Washington, DC 20016

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| 2. Health professional? | 3. Occupation | 4. Initial reporter also sent report to FDA |
|---|---|---|
| (X) Yes ( ) No | physician | ( ) Yes ( ) No (X) Unk |

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

ADVERSE EVENT REPORTING SYSTEM